

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No: 37697/0002

In re patent application of

Edward W. MERRILL *et al.*

Serial No.: To be assigned

Filed: Concurrently herewith

For: Radiation and Melt Treated Ultra High Molecular Weight  
Polyethylene Prosthetic Devices

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination, please enter the following amendments.

**IN THE SPECIFICATION**

Page 1, please replace the text at lines 3-10 with -- This application is a continuation of U.S. Serial No. 09/572,324, filed May 18, 2000, which is a continuation of U.S. Serial No. 08/798,638, filed February 11, 1997, which is a continuation-in-part of 08/726,313, filed October 2, 1996, which is a continuation-in-part of U.S. Serial No. 08/600,744, filed February 13, 1996, which issued as U.S. Patent No. 5,879,400. The entire contents of each of the above-identified applications are hereby incorporated by reference. --

**IN THE CLAIMS**

Please cancel claims 1-123 without prejudice or disclaimer. Please add the claims set forth below.

124. A process for preparing a medical implant having an improved balance of wear properties and oxidation resistance comprising the steps of:

irradiating a preform of ultrahigh molecular weight polyethylene to form free radicals;

annealing the irradiated preform by heating in a substantially oxygen-free atmosphere at a temperature above about 150°C, for a time sufficient to recombine substantially all of the free radicals and cross-link the ultrahigh molecular weight polyethylene;

cooling the cross-linked preform while maintaining a substantially oxygen-free atmosphere;

forming a medical implant from the cross-linked preform;

packaging the medical implant in an air-permeable package; and

sterilizing the packaged implant using non-irradiative methods.

125. A process for preparing a medical implant having an improved balance of wear properties and oxidation resistance comprising the steps of:

Continuation of U.S. Serial No. 09/572,324

irradiating a preform of ultrahigh molecular weight polyethylene to form free radicals;

annealing the irradiated preform by heating in a substantially oxygen-free atmosphere at a temperature above about 150°C, to cross-link the ultrahigh molecular weight polyethylene;

cooling the cross-linked preform while maintaining a substantially oxygen-free atmosphere;

forming a medical implant from the cross-linked preform.

126. A medical implant prepared according to the process of claim 124.

127. A medical implant prepared according to the process of claim 125.

128. A cross-linked ultrahigh molecular weight polyethylene having a swell ratio of less than about 5 and an oxidation level of less than about 0.2 carbonyl area/mil sample thickness after aging the ultrahigh molecular weight polyethylene at 70°C, for 14 days in oxygen at a pressure of about 5 atmospheres.

129. A medical implant comprising the ultrahigh molecular weight polyethylene of claim 128.

130. A process for preparing a medical implant having an improved balance of wear properties and oxidation resistance comprising the steps of:

irradiating a preform of ultrahigh molecular weight polyethylene to form free radicals;

annealing the irradiated preform by heating at a temperature above about 150°C, for a time sufficient to recombine substantially all of the free radicals and cross-link the ultrahigh molecular weight polyethylene;

cooling the cross-linked preform;

forming a medical implant from the cross-linked preform;

packaging the medical implant in an air-permeable package; and

sterilizing the packaged implant using non-irradiative methods.

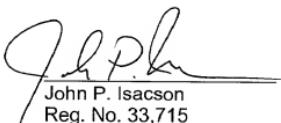
Continuation of U.S. Serial No. 09/572,324

**REMARKS**

Applicants have canceled claims 1-123 without prejudice or disclaimer of the subject matter recited therein, and applicants expressly reserve all rights to such subject matter. Applicants have added claims 124-130, which are copied from or closely paraphrase claims from U.S. Patent No. 6,017,975 to Saum *et al.*, which issued January 25, 2000 (copy enclosed). Claims 124, 125, 128 and 130 correspond respectively to claims 1, 15, 32 and 35 of the '975 patent. Claims 126 and 127 correspond to claim 31 of the '975 patent. Claim 129 corresponds to claim 34 of the '975 patent.

By filing of this application and preliminary amendment, applicants have fully complied with the requirements of 35 USC § 135(b)(1). Applicants request examination of the claims. A first office action on the merits is awaited.

Respectfully submitted,



John P. Isaacson  
Reg. No. 33,715

January 19, 2001

HELLER, EHRMAN,  
WHITE & McAULIFFE LLP  
815 Connecticut Avenue, N.W.  
Suite 200  
Washington, D.C. 20006  
Tel: 202-263-8900  
Fax: 202-785-8877



26633  
PATENT TRADEMARK OFFICE